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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: RONALD A. SCHACHAR
United States Serial No.: 09/589,626
Filed: June 7, 2000
Title: SCLERAL PROSTHESIS FOR THE TREATMENT OF
PRESBYOPIA AND OTHER EYE DISORDERS
Examiner: David H. Willse
Art Group Unit: 3738

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Commissioner for Patents
P.O. Box 1450
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1. Appellant's Reply Brief Under 37 C.F.R. §1.193(b) (in triplicate);
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Sir:

APPELLANT'S REPLY BRIEF UNDER 37 C.F.R. §1.193(b)

This Reply Brief is in furtherance of the Notice of Appeal filed in this application on October 14, 2003 and received in the U.S. Patent and Trademark Office on October 17, 2003. This Reply Brief is filed in response to the Examiner's Answer dated March 9, 2004. Because May 9, 2004 is a Sunday the time for filing this Reply Brief is extended to Monday, May 10, 2004.

This reply brief is transmitted in triplicate (37 C.F.R. §1.192(a)).

This brief contains these items under the following headings and in the order set forth below

(37 C.F.R. §1.192(c)):

- I REAL PARTY IN INTEREST
- II RELATED APPEALS AND INTERFERENCES
- III STATUS OF CLAIMS
- IV STATUS OF AMENDMENTS
- V SUMMARY OF INVENTION
- VI ISSUES
- VII GROUPING OF CLAIMS
- VIII ARGUMENTS
 - A. ARGUMENTS - REJECTION UNDER 35 U.S.C. § 101
 - B. ARGUMENTS - REJECTION UNDER 35 U.S.C. § 102(b)
 - C. ARGUMENTS - REJECTION UNDER 35 U.S.C. § 103(a)
- IX APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

The final page of this brief before the beginning of the Appendix of Claims bears the attorney's signature.

I REAL PARTY IN INTEREST (37 C.F.R. §1.192(c)(1))

The real party in interest in this appeal is RAS Holding Corporation.

II RELATED APPEALS AND INTERFERENCES (37 C.F.R. §1.192(c)(2))

With respect to other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal, there are no such appeals or interferences.

III STATUS OF CLAIMS (37 C.F.R. §1.192(c)(3))

The status of the claims in this application are:

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

There are twenty four (24) claims in the application (Claims 1-24).

B. STATUS OF ALL THE CLAIMS

1. Claims previously canceled: None.
2. Claims withdrawn from consideration but not canceled: None.
3. Claims pending: Claims 1-24.
4. Claims allowed: Claims 22-24.
5. Claims objected to: None.
6. Claims rejected: Claim 1-21.

C. CLAIMS ON APPEAL

The claims on appeal are 1-21.

IV STATUS OF AMENDMENTS (37 C.F.R. §1.192(c)(4))

No amendment was filed subsequent to the final rejection set forth in the Office Action of August 14, 2003.

V SUMMARY OF INVENTION (37 C.F.R. §1.192(c)(5))

The present invention relates to the treatment of presbyopia and other eye disorders. Presbyopia is the universal decrease in the amplitude of accommodation of the eyes that is typically observed in individuals over forty years of age. In an individual who has normal vision, the ability to focus on near objects is gradually lost, and the individual then needs glasses for tasks requiring near vision, such as reading. In the present invention presbyopia is treated by increasing the amplitude of accommodation of an eye by increasing the effective working distance of a muscle in the eye that is referred to as a ciliary body. The effective working distance of the ciliary body is increased by expanding the sclera of the eye in the region of the ciliary body. The expansion may be accomplished by implanting a prosthesis 100 within a scleral pocket surgically formed within the sclera of the eye in the region of the ciliary body. When the prosthesis 100 is located within the scleral pocket, the prosthesis 100 applies force to the scleral pocket and causes the sclera to expand. This increases the effective working distance of the muscle of the ciliary body and allows the lens of the eye to focus on near objects.

One advantageous embodiment of the prosthesis 100 of the present invention comprises a body 100 having a first end 105a and a second end 105b (Figures 1-5, Specification Page 13, Line 14 to Page 17, Line 7). The body 100 has a top surface 110 that contacts the scleral tissue within the scleral pocket when the prosthesis 100 is located within the scleral pocket. The body 100 has a bottom surface 120 that contacts the scleral tissue within the scleral pocket when the prosthesis 100 is located within the scleral pocket. Ends 105a, 105b and top surface 110 and bottom surface 120 provide a means for stabilizing the prosthesis 100 within a surgically formed scleral pocket thereby enabling prosthesis 100 to substantially permanently exert an outward force on the scleral pocket to elevate the portion of the sclera attached thereto to increase the effective working distance of the ciliary muscle. (Specification, Page 15, Lines 13-19).

VI ISSUES (37 C.F.R. §1.192(c)(6))

- A. Whether the Examiner erred in finally rejecting Claims 1-21 under 35 U.S.C. § 101 for allegedly claiming non-statutory subject matter.
- B. Whether the Examiner erred in finally rejecting Claims 1-7 and Claims 12-17 under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,354,331 to *Schachar*.
- C. Whether the Examiner erred in finally rejecting Claims 8-11 and Claims 18-21 under 35 U.S.C. § 103(a) as being obvious in view of United States Patent No. 5,354,331 to *Schachar*.

VII GROUPING OF CLAIMS (37 C.F.R. §1.192(c)(7))

Claims 1-21 were rejected under 35 U.S.C. § 101 as allegedly claiming nonstatutory subject matter. Claims 1-7 and Claims 12-17 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Schachar*. Claims 8-11 and Claims 18-21 were rejected under 35 U.S.C. § 103(a) as being obvious in view of *Schachar*. For purposes of this appeal, the pending claims will be grouped together as follows:

Group A - Claims 1-21 (all pending rejected claims);

Group B - Claims 1-7 and Claims 12-17; and

Group C - Claims 8-11 and Claims 18-21.

Patentability of the claims within each group is argued separately below.

VIII ARGUMENTS

A. ARGUMENTS - Rejection under 35 U.S.C. §101 (37 C.F.R. §1.192(c)(8)(v)):

In the Examiner's Answer the Examiner stated "In regard to the rejection under 35 U.S.C. § 101, since scleral contact (e.g., claim 1, line1) and scleral expansion (e.g., claim 1, line 2) are positively recited, the sclera itself is positively recited in combination with the prosthesis." (Examiner's Answer, Page 3, Lines 10-12). The Appellant respectfully points out that the claimed invention is a prosthesis. By definition a prosthesis is not part of a human body. The prosthesis of the claimed invention contacts and interacts with a part of a human body – specifically, the sclera of an eyeball. The Appellant respectfully submits that it is very clear that Claims 1-21 of the patent application are directed to the prosthesis and not to the sclera of the

eyeball. Therefore, Claims 1-21 do not claim nonstatutory subject matter. The Appellant respectfully traverses the Examiner's assertion that "the sclera itself is positively recited in combination with the prosthesis" in Claims 1-21.

The Examiner also stated that "The Appellant has opted not to use the claim language suggested by the examiner (Paper No. 10: page 2, lines 9-11) for overcoming this rejection." (Examiner's Answer, Page 3, Lines 12-14). The Appellant previously used the claim language suggested by the Examiner to amend Claim 22. (Amendment of June 26, 2003). The Appellant did not use the claim language suggested by the Examiner to amend Claims 1-21 because the Appellant believes that Claims 1-21 are in proper form as they are currently written.

The Examiner's Answer contains a copy of notice signed by Commissioner Donald J. Quigg on April 7, 1987. The notice states "A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. § 101." The Appellant agrees with this statement. The Appellant disagrees with the Examiner's conclusion that Claims 1-21 are directed to or include a human being within their scope.

The April 7, 1987 notice suggests using the term "non-human" in claim language when it is necessary to distinguish a claim that would otherwise include a human being within its scope. In the present case adding the term "non-human" would be unnecessary because by definition a prosthesis is a article of manufacture and is therefore "non-human."

The Appellant respectfully requests that the Examiner's rejection of Claims 1-21 under 35 U.S.C. § 101 be withdrawn.

B. ARGUMENTS - Rejection under 35 U.S.C. §102(b) (37 C.F.R. §1.192(c)(8)(iii)):

In the Examiner's Answer the Examiner stated "In regard to the rejection under 35 U.S.C. § 102(b) based upon *Schachar*, US 5,354,331, it is first noted that the term "elongated" (e.g., page 10, line 3, of the Appellant's Brief) does not appear anywhere in the Appellant's claims 1-21, nor is there any claim limitation that ends be free or unattached." (Examiner's Answer, Page 3, Lines 17-20).

The Appellant notes that the term "elongated" is a term that was used by the Examiner in rejecting Claims 1-7 and Claims 12-17 in the Office Action of December 26, 2002. "Claims 1-7 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by *Schachar*, US 5,354,331. Some of the disclosed embodiments are elongated with first and second ends, as seen from column 7, lines 1-12; column 8, lines 22-26; etc." (December 26, 2002 Office Action, Page 4, Lines 6-8) (Emphasis added). The term "elongated" is a term that the Examiner has used to characterize some allegedly anticipatory embodiments in the *Schachar* reference. The Appellant's use of the word "elongated" in the Appeal Brief is in response to the Examiner's arguments. The Appellant respectfully disagrees with the Examiner's characterization of the *Schachar* reference as teaching embodiments that are "elongated with first and second ends." It is immaterial that the word "elongated" does not appear in Claims 1-21.

The Examiner also stated that the claims do not contain a claim limitation that the ends are "free" or "unattached." The Appellant respectfully submits that the term "end" in the claims inherently refers to a "free" end or "unattached" end. It is well established that claim elements are to be interpreted and construed in light of the disclosure in the specification of the patent application.

“While the claims . . . limit the invention, and specifications cannot be utilized to expand the patent monopoly, . . . claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention.” *United States v. Adams*, 383 U.S. 39, 48-49, 148 USPQ 479, 482 (1966). The specification of the patent application clearly indicates that the term “end” means and refers to a “free” or “unattached” end.

The ordinary meaning of the word “end” also means and refers to a “free” or “unattached” end. “[W]ords will be given their ordinary and accustomed meaning unless it appears that the inventor used them differently.” *Universal Oil Prod. Co. v. Globe Oil & Ref. Co.*, 137 F.2d 3,6, 58 USPQ 504, 508 (7th Cir. 1943), *aff’d*, 322 U.S. 471, 61 USPQ 382 (1944). The term “end” in its ordinary meaning is properly used to claim the elements of the Appellant’s invention. The plurality of “ends” identified by the Examiner in the structure disclosed in the *Schachar* reference are portions of intermediate subparts that are coupled together to form a complete band or ring. A complete band or ring has no “end” as that term is used in Claims 1-7 and Claims 12-17.

The Appellant’s interpretation is the interpretation that should be adopted. “[I]f the claim [is] fairly susceptible of two constructions, that should be adopted which will secure to the patentee his actual invention.” *Smith v. Snow*, 294 U.S. 1, 14 (1935). The Appellant respectfully submits that the Appellant has properly claimed the invention in Claims 1-7 and Claims 12-17 and that the claims are not anticipated by the *Schachar* reference.

The Examiner’s Answer also stated that “The examiner disagrees with the Appellant’s assertion that in the Schachar patent, “[t]he ‘overlapping ends’ cease to exist after the scleral expansion band has been formed” (page 11, lines 8-9, of the Appellant’s Brief), especially since the

overlapping ends play a role in facilitating circumferential adjustments of the (previously formed) scleral expansion band of Schachar (US 5,354,331: column 7, lines 4-12). (Examiner's Answer, Page 2, Line 20 to Page 3, Line 2). The Appellant's Brief stated "The 'overlapping ends' cease to exist after the scleral expansion band has been formed." (Appellant's Brief, Page 11, Lines 8-9) (Emphasis added). That is to say, after the complete band or ring of the *Schachar* device has been completely formed (including the circumferential adjustments and the fastening together of the overlapping ends) the overlapping ends cease to exist in the sense that they no longer are capable of moving with respect to each other. They are fastened together to form a unitary ring structure.

The *Schachar* reference states "The scleral expansion band may also be made from a plurality of parts that can be assembled prior to use or may be installed separately to form a complete band." (*Schachar*, Column 7, Lines 1-3). It is clear that the constituent parts of the *Schachar* complete band are assembled (i.e., fastened together) prior to use. The constituent parts are not used separately. The constituent parts must be formed into a complete band before they can be used. That is, the "plurality of parts" (*Schachar*, Column 7, Line 2) and the "strip of material" (*Schachar*, Column 7, Line 5) must first be formed into a complete band before they can be used. After the complete band has been formed, the "plurality of parts" or the "strip of material" forms a complete band (a ring structure) that does not have first and second ends. A ring structure has no first and second end.

For the reasons stated above, the Appellant respectfully submits that the *Schachar* reference does not anticipate the unique and novel elements of the Appellant's invention. The Appellant respectfully requests that the rejection of Claims 1-7 and Claims 12-17 under 35 U.S.C. § 102(b) be withdrawn.

C. ARGUMENTS - Rejection under 35 U.S.C. §103(a) (37 C.F.R. §1.192(c)(8)(iii)):

The Applicant respectfully submits that the Patent Office has not established a *prima facie* case of obviousness with respect to the Applicant's invention. The Applicant hereby incorporates by reference all of the comments and arguments that the Applicant has previously made in connection with the Examiner's rejection of claims under 35 U.S.C. § 102.

In the Examiner's Answer the Examiner stated "In regard to the rejection under 35 U.S.C. § 103(a) based upon Schachar, US 5,354,331, if the cross-sectional dimensions of the Schachar band slidable ends were not modified, then the resulting bulge would create an unwanted asymmetry in the effective working distance of the ciliary muscle and would even hinder *in situ* circumferential adjustments." (Examiner's Answer, Page 4, Lines 7-10). The Examiner is identifying a problem that allegedly exists in the operation of the *Schachar* device. However, the problem that the Examiner is identifying is a problem that was not mentioned, suggested or even hinted at in the *Schachar* reference.

The Examiner goes on to "invent" a solution to the problem using complementary concave and convex tracking surfaces. "Complementary concave and convex (e.g., groove and ridge) tracking surfaces that maintain generally uniform band cross-sections would alleviate these problems and would provide smooth guiding surfaces for relative movement of the slidable ends via the tangential screw mechanism." (Examiner's Answer, Page 4, Lines 13-16).

The *Schachar* reference does not mention, suggest or even hint at the use of (1) concave surfaces, or (2) convex surfaces, or (3) complementary concave and convex surfaces. The *Schachar* reference does not even mention, suggest or even hint at the existence of a problem that the concave

and convex surfaces are supposed to solve.

The Examiner stated that “Complementary concave and convex surfaces at the ends of the band would have been obvious in order that the overlapping ‘ends may slide past one another’ (column 7, lines 6-7) and ‘[t]he length of the overlap may be adjusted’ (column 7, line 8-9) while maintaining a ring-like shape (via the tracking of the engaging concave and convex surfaces) and a substantially uniform thickness, such being especially desirable when the band is positioned within the sclera (column 7, line 37).” (August 14, 2003 Office Action, Page 3, Lines 2-7). The Applicant respectfully disagrees with the Examiner’s characterization of the *Schachar* reference as teaching “complementary concave and convex surfaces at the ends of the band.”

As previously stated, the *Schachar* reference does not mention, suggest or even hint at the use of (1) concave surfaces, or (2) convex surfaces, or (3) complementary concave and convex surfaces. The *Schachar* reference does mention using a scleral expansion band that is adjustable in circumference. “For example, the band may be formed from a strip of material, e.g., metal or synthetic resin, with overlapping ends so that the ends may slide past one another thereby adjusting the circumference of the band.” (*Schachar*, Column 7, Lines 3-7). But there is no mention of concave or convex surfaces.

As previously stated, the “overlapping ends” of the constituent parts are “assembled” (i.e. fixed together) to make a complete band prior to use. This is why the *Schachar* device does not have “the potential of imposing tissue trauma at the end edges” as the Examiner assumed or supposed that it would (Examiner’s Answer, Page 4, Line 12). This is also why the *Schachar* device would not “unduly burden the screw mechanism with shear stresses and the like” as the Examiner

assumed or supposed that it would (Examiner's Answer, Page 4, Line 13).

The Appellant respectfully asserts that the Examiner has inappropriately applied hindsight when combining the teachings of the *Schachar* reference and the concept of using concave or convex surfaces in a scleral prosthesis in order to arrive at the claimed invention recited in Claims 8-11 and Claims 18-21. The teaching of using concave or convex surfaces in a scleral prosthesis comes from the Appellant's patent application. Therefore, the Appellant respectfully submits that the rejection of Claims 8-11 and 18-21 under 35 U.S.C. §103(a) should be withdrawn.

Further, even if the concept of concave and convex surfaces could be properly combined with the *Schachar* reference, the combination would still not teach, suggest or hint at the Appellant's invention. Even if complementary concave and convex surfaces were used in the overlapping ends of the *Schachar* scleral expansion band, there is no teaching in *Schachar* to use individual sections of the scleral expansion band separately. The individual sections are always used in a completely formed unitary scleral expansion band.

For the reasons stated above, the Appellant respectfully submits that the *Schachar* reference does not render obvious the unique and novel elements of the Appellant's invention. Therefore, the rejection of Claims 8-11 and 18-21 under 35 U.S.C. § 103(a) has been overcome. The Appellant respectfully requests that the rejection of Claims 8-11 and 18-21 under 35 U.S.C. § 103(a) be withdrawn.


SUMMARY

For the reasons given above, the Appellant respectfully requests reconsideration and allowance of the claims and that this patent application be passed to issue.

Respectfully submitted,

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Date: May 10, 2004



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IX APPENDIX OF CLAIMS INVOLVED IN THE APPEAL (37 C.F.R. §1.192©)(9))

The text of each claim involved in the appeal is as follows:

1. A prosthesis that contacts the sclera of an eyeball, said prosthesis comprising a body having a first end and a second end, said body having a planform that expands said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball.

2. The prosthesis set forth in Claim 1 wherein said body further comprises a top surface that contacts ocular tissue within a pocket surgically formed within the sclera of the eyeball.

3. The prosthesis set forth in Claim 2 wherein said top surface is circumferentially shaped and exerts an outward force on the scleral pocket to elevate the portion of the sclera attached thereto to increase the effective working distance of the ciliary muscle of the eyeball.

4. The prosthesis set forth in Claim 2 wherein said body further comprises a means for stabilizing said prosthesis within said surgically formed pocket within the sclera of the eyeball.

5. The prosthesis set forth in Claim 4 wherein said stabilizing means includes a bottom surface that contacts ocular tissue within said surgically formed pocket.

6. The prosthesis set forth in Claim 5 wherein an ocular tissue contact area of said bottom surface of said body is at least substantially equal to an ocular tissue contact area of said top surface of said body.

7. The prosthesis set forth in Claim 4 wherein said stabilizing means includes at least one of said first end and said second end that fixes said body within said surgically formed pocket.

8. The prosthesis set forth in Claim 7 wherein said at least one of said first end and said second end has a partially concave top surface.

9. The prosthesis set forth in Claim 7 wherein said at least one of said first end and said second end has a partially convex top surface.

10. The prosthesis set forth in Claim 7 wherein said at least one of said first end and said second end has a partially concave bottom surface.

11. The prosthesis set forth in Claim 7 wherein said at least one of said first end and said second end has a partially convex bottom surface.

12. A prosthesis that contacts the sclera of an eyeball, said prosthesis comprising a body having a first end and a second end, said body having a planform that expands said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball and further means for stabilizing said prosthesis within said surgically formed pocket within the sclera of the eyeball.

13. The prosthesis set forth in Claim 12 wherein said body further comprises a top surface that contacts ocular tissue within a pocket surgically formed within the sclera of the eyeball.

14. The prosthesis set forth in Claim 13 wherein said top surface is circumferentially shaped and exerts an outward force on the scleral pocket to elevate the portion of the sclera attached thereto to increase the effective working distance of the ciliary muscle of the eyeball.

15. The prosthesis set forth in Claim 12 wherein said stabilizing means includes a bottom surface that contacts ocular tissue within said surgically formed pocket.

16. The prosthesis set forth in Claim 15 wherein an ocular tissue contact area of said bottom surface of said body is at least substantially equal to an ocular tissue contact area of said top surface of said body.

17. The prosthesis set forth in Claim 12 wherein said stabilizing means includes at least one of said first end and said second end that fixes said body within said surgically formed pocket.

18. The prosthesis set forth in Claim 17 wherein said at least one of said first end and said second end has a partially concave top surface.

19. The prosthesis set forth in Claim 17 wherein said at least one of said first end and said second end has a partially convex top surface.

20. The prosthesis set forth in Claim 17 wherein said at least one of said first end and said second end has a partially concave bottom surface.

21. The prosthesis set forth in Claim 17 wherein said at least one of said first end and said second end has a partially convex bottom surface.

The text of each allowed claim is as follows:

22. A prosthesis for contacting the sclera of an eyeball, said prosthesis comprising:
a body having at least one end portion which is wider than an incision forming a scleral pocket for containing said prosthesis, a remainder of said body extending from said at least one end portion in a direction substantially perpendicular to a width dimension of said at least one end portion,
a bottom surface of said body having at least one concave region separated from an end of said body by a flat surface,
said at least one concave region having a radius of curvature of approximately five hundred microns,
whereby said prosthesis exerts an outward force on said scleral pocket to elevate a portion of the sclera attached thereto when said prosthesis is disposed within said scleral pocket, and
wherein said at least one end portion is configured to extend beyond said scleral pocket.
23. The prosthesis as set forth in Claim 22, wherein said body includes a major convex surface having a radius of curvature of approximately nine millimeters.
24. The prosthesis as set forth in Claim 22, wherein end portions of said body are sloped.